**Standard Operating Procedure**

| SUBJECT: Application's Standard Library Maintenance under the caBIG™ Program | SOP No.: CR-005 |
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| | Version No.: 1.0 |
| | Effective Date: 10/31/2005 |
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# Standard Operating Procedure –

# Application's Standard Library Maintenance under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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**Note**: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

## Revision History

| Revision | Date | Author | Change Reference | Reason for Change |
|---|---|---|---|---|
| 1.0 | 09/19/05 | SOP Working Group | N/A | Initial release. |
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## 1. Purpose

This SOP describes the process by which the application's Standard Library for a clinical data management application is managed to support of clinical research trials conducted under the caBIG™ Program. The objective is to ensure that the application's standard library is managed appropriately, to enable standards and sustain data interoperability.

## 2. Scope

This SOP applies to the maintenance of the application's standard library for the clinical data management applications in support of clinical research trials under the caBIG™ Program at the National Institute of Cancer (NCI).

## 3. Requirements

3.1 Common Data Elements (CDEs) that electronically represent paper case report form (CRF) enable the electronic collection of clinical trial data are to be stored and managed in the application's standard library.

3.2 The application's Standards Librarian manages the CDEs used by Study Designers to create clinical research trials in a clinical data management application. These activities include: Activate CDEs for use in production, retire CDEs that are no longer used or have been updated or modified, and work with the caDSR Curator when new CDEs are required to support clinical trials.

3.3 The *SOP for CDE Curation* should be followed when new elements need to be created and added to the application's standard library.

## 4. References/Regulations/Guidelines

| Section | SOP Number | Title |
|---|---|---|
| 4.1 | N/A | CDISC Glossary |
| 4.2 | N/A | ICH E9 |
| 4.3 | N/A | ICH E6 Good Clinical Practice |
| 4.4 | CR-004 | SOP for CDE Curation |
| 4.5 | CR-001 | SOP for Study Setup |

## 5. Roles & Responsibilities

| Role | Responsibility |
|---|---|
| Study Designer | • Work with the Study Coordinator and the application's Standard Librarian to select appropriate CDEs to support protocol data requirements. |
| Study Coordinator | • Work with the Study Designer and the application's Standards Librarian to review and select CDEs in support of protocol requirements. |
| Application's Standards Librarian | • Work with the Study Design, the Study Coordinator to select CDEs that support protocol data collection requirements.<br>• Manage all CDEs and other metadata objects within the clinical data management application to support the planning, set-up, and execution of the clinical research trial (e.g., activates for production, retires objects).<br>• Manage the process of loading and activating new CDEs. |

## 6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

| Title | Description |
|---|---|
| 1) Procedure Description for Application's Standard Library Maintenance | This document provides instructions for the management of CDEs and other metadata objects within the application's Standards Library. It provides guidance to assure that the application's standards library is managed in a consistent manner. |
| 2) Process Flow for Application's Standard Library | This document identifies the workflow activities, by role, for the steps identified in the Procedure for Managing and Maintaining the Application's Standard Library Process Flow |